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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,941	04/30/2001	James F. Hemerick	6530.0278	8636

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EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/843,941

Applicant(s)

HEMERICK ET AL.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,45,47-57,59-65,67 and 68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11,45,47-57,59-65,67 and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 11, 45, 48, 50-53 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seguin et al. (6,666,883) in view of Sullivan et al. (5,968,052). Seguin et al. disclose outer tubular structure 16, inner elongated structure 15, stent accommodating area (just distal to the abutment described in col. 5, lines 28-34) and an external tubular structure contact area (the abutment described in col. 5, lines 28-34) which slides against the interior surface of the outer tubular structure 16 since it is radially enlarged relative to the remainder of inner structure 15. et al. Seguin fail to disclose a translucent region at the distal end of the outer tubular structure 16. However, Sullivan et al. teach that the outer tubular structure 14 of a stent delivery system should transmit light therethrough (i.e. be translucent) so that the stent therein may be visually inspected (col. 3, lines 24-33). It would have been obvious to make the outer tubular structure 16 of Seguin et al. translucent so that it too would have this advantage. With this modification, the Seguin et al. translucent outer tubular structure 16 would include a translucent region (between radiopaque rings 21 and 22, for example) which would have a length less than the constrained length of stent 1 as claimed, since radiopaque rings 21 and 22, (like radiopaque rings 42 and 44 on translucent outer tubular

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structure 14 of Sullivan et al.) are not translucent and thus define ends of a translucent region. Note that the transparent material of Sullivan et al. is inherently translucent to some extent since no material is perfectly transparent. As to claims 48 and 50, Seguin et al. fail to disclose at least one marker band on the inner elongated structure. However, Sullivan et al. teach that the inner elongated structure of a stent delivery system should include a marker band (e.g. 36) in order to provide an indication of the position of the stent (col. 3, lines 1-13). It would have been obvious to include a marker band on the inner elongated structure 12 of Seguin et al. so that it too would have this advantage. As to claim 51, Seguin et al. fail to disclose the steps of retracting the stent back into the outer tubular structure and then repositioning the stent delivery system. However, retracting the Seguin et al. stent back into the outer tubular structure and then repositioning the stent delivery system when it is determined that the stent is not initially properly positioned would have been obvious since it was well known in this art to so retract and reposition stents for this reason. As to claim 53, Seguin et al. fail to show Pellethane as the material for the inner tubular structure. However, using Pellethane as the material for the inner tubular structure would have been obvious since it

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is well known as a desirable material for this use as indicated on page 2, lines 8-10 of applicant's specification. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03).

Claims 47 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seguin et al. (5,306,294) in view of Sullivan et al. (5,968,052) as applied to claims 11, 45, 48, 50-53 and 61 above, and further in view of Hofmann et al. (5,810,837). Seguin et al. fail to disclose a gap between an external surface of the external tubular structure and the inner surface of the outer tubular structure 20. However, Hofmann et al. teach that there should be a gap between the external surface of the external tubular structure 10 and the inner surface of the outer tubular structure 3 (the outer diameter C of member 10 is 4.5 mm while the inner diameter B of outer tubular structure 3 is 4.6 mm as indicated in col. 4, line 38) apparently in order to insure that the inner elongated structure 10, 9, 7 is able to slide relative to outer tubular structure 3 with minimal friction. It would have been obvious to provide such a gap between the Seguin et al. external surface of the external tubular structure and the inner surface of the outer tubular structure 16 so that it too would have this advantage.

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Claims 54, 55, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seguin et al. (5,306,294) in view of Sullivan et al. (5,968,052) as applied to claims 11, 45, 48, 50-53 and 61 above, and further in view of Winston et al. (5,306,294). Seguin et al. disclose only a single external tubular contact area rather than a plurality of external tubular contact areas. However, Winston et al. teach that an inner structure of a stent delivery device should include a plurality of external tubular contact areas 14 in order to obtain the advantage of locating stents therebetween so that a plurality of stents can be deployed from a single delivery device (col. 4, lines 50-60). It would have been obvious to include a plurality of external tubular contact areas on the Seguin et al. inner elongated structure 15 so that it too would have this advantage.

Claims 56, 57, 59, 60, 64, 65, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seguin et al. (5,306,294) in view of Sullivan et al. (5,968,052) and Winston et al. (5,306,294) as applied to claims 54, 55, 62 and 63 above, and further in view of Burns (5,100,381). Seguin et al. fail to disclose each subsequently proximal external structure increasing in durometer. However, Burns teaches that the distal portion of a catheter should be more flexible than the proximal portion in order to allow the catheter to be advanced through

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the rather tortuous paths of the arteries while maintaining pushability (col. 2, lines 30-34 and col. 3, line 65 to col. 4, line 6). It would have been obvious to make the distal portion of the Seguin et al. catheter 15 more flexible than the proximal portion so that it too would have this advantage. With this modification, the distal portion of the Seguin et al. catheter 15 (which would include a distal flange) would be made of a material which is more flexible (with a low durometer) than a proximal portion of the catheter 15 (which would include a proximal flange) made of a high durometer, stiffer material.

Applicant's arguments with respect to claims 11, 45, 47-57, 59-65, 67 and 68 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

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statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

mht
11/19/04



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731